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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,229	10/02/2006	Eva Blychert	1103326-0902	7595

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PATENT DEPARTMENT
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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,229	BLYCHERT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 18* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 5, 8 - 13, 15 - 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed April 16, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Response to Arguments

1. Applicant's arguments with respect to the art rejections under 35 USC 102(b) and 35 USC 103(a) have been considered but are moot in view of the new ground(s) of rejection. Where arguments presented by Applicant remain relevant to the new rejection, those arguments are addressed at the end of each new rejection made below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 5, 8, 9, 12, 13 and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olovson et al. (WO 94/25070) in view of Bergstrand et al. (US 5,753,265).

Olovson et al. discloses a composition comprising a proton pump inhibitor and a gelling agent for the treatment of gastric acid related diseases in animals (abstract). Enteric coated, dry particles of the proton pump inhibitor are mixed with dry gelling agent(s) so that when water is added, a paste-like gel is formed (p 3, ln 4 – 13). Other substances such as flavoring substances may be incorporated into the composition (p 7, ln 30 – 31). Examples given for the active ingredient include omeprazole, lansoprazole and pantoprazole (p 5). The volume administered to the patient is in the

range of 5 – 50 mL (p 7, ln 27 – 28). In the examples (beginning on p 9), omeprazole enteric-coated pellets prepared according to US 4786505 are prepared. In example 2 (p 10), the enteric coated particles, xanthan gum and citric acid are combined to form a solid composition. This forms a gel in a syringe when 10 mL of water is added.

Olovson et al. does not disclose a proton pump inhibitor dosage of 1 - 100 mg or the administration of an aqueous suspension of enteric coated proton pump inhibitor containing particles to a pediatric patient.

Bergstrand et al. discloses multiple unit tableted dosage form which may be dispersed in an aqueous liquid and given to patients with swallowing disorders or in pediatrics wherein the suspension of dispersed enteric coated layered units is given orally or through a naso-gastric tube (col 5, ln 53 – 62). The daily dose will generally be in the range of 1 - 1000 mg but varies depending on the individual requirements of the patient, the administration mode and disease (col 10, ln 36 – 43). In examples 2 and 3, the total dose present in the dosage form was about 20 mg (col 11, ln 31 – col 12, ln 48).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to administer the composition taught by Olovson et al. with a thickener to a pediatric patient. The presence of a thickener increases the viscosity, limiting the rate at which the particulate matter would settle out of the composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Berstrand et al. discloses that the compositions as taught by Olovson et al. without the thickener can be

administered to pediatric patients. The amount of active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results based on factors such as those disclose by Bergstrand et al., including the condition of the patient and disease being treated. One of ordinary skill would also optimize the amount of thickener and thus the viscosity of the composition to prepare a final composition that would prevent settling of the particulate matter while not being so viscous as to be difficult to administer through the naso-gastric tube.

In regards to the Olovson et al. reference, Applicant has argued that the requirement of a paste-like gel consistency renders the formulation unsuitable for its intended purpose. The compositions of Olovson et al. may be described as paste like, but they can be administered via syringe and all the method claims require is oral administration via gastric tube or syringe. Thus, administration of a paste like composition to the tongue of an animal or pediatric patient, which is subsequently swallowed meets the limitations in the rejected claims. The particular viscosity limitations recited in claims 8 and 9 do not specify a temperature at which these viscosities are measured. Particularly in view of Bergstrand et al. one of ordinary skill in the art would realize that dispersions of particulates can be administered to pediatric patients via a naso-gastric tube. One of ordinary skill in the art would be aware of the

possibility of "clogging" by the particles and would size the particles in the suspension appropriately.

6. Claims 1 – 5, 8, 9, 12, 13 and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olovson et al. (WO 94/25070) and Bergstrand et al. (US 5,753,265) further in view of Calanchi et al. (US 6,261,602).

As discussed in greater detail above, Olovson et al. and Bergstrand et al. teach administration of a suspension of enteric coated pellets of proton pump inhibitors and a thickener. These preparations can be administered to pediatric patients either orally or through as naso-gastric tube to treat gastrointestinal disorders.

Neither reference discloses the use of starch as the thickener.

Calanchi et al. discloses thickening agent which dissolve in water and increase the viscosity of the aqueous media such as water (col 3, ln 64 – col 4, ln 1). Examples given of thickening agents include xanthan gum, guar gum, tragacanth, karaya gum and modified corn starch (col 4, ln 1 – 8). Calanchi et al. also discloses that the desired particle size is between 250 μm and 850 μm (col 5, ln 47 – 49). A particle size above 850 μm increases the time required to obtain a solution with a viscosity that can keep the particles in solution while particles sizes below 200 μm can lead to lump formation (col 5, ln 49 – 54).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and administer a suspension of enteric coated proton pump particles and a gelling agent as taught by Olovson et al. and to use starch as the gelling

agent, taught by Calanchi et al. to be functionally equivalent to the gelling agents taught and used by Olovson et al. It also would be obvious to prepare particles with a diameter of 250 µm to 750 µm, taught by Calanchi et al. to reduce lump formation while not increasing the time necessary to prepare a solution of the appropriate viscosity.

Applicant has argued that Calanchi et al. teaches away because it teaches the administration of aqueous suspension from a glass or poured directly into the mouth and fails to give "any meaningful suggestion of using a viscous medium" to facilitate administration through a thin gastric tube. The syringe or naso-gastric tube administration route is taught by Olovson and Bergstrand et al. The small differences in how the composition is orally administration (from a glass, poured in directly in to the mouth, introduced into the mouth via syringe or via naso-gastric tube) does not negate the teaching of functional equivalence between the various thickener ingredients of Calanchi et al. and Olovson et al.

7. Claims 1 – 5, 8 – 13 and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olovson and Bergstrand et al. as applied to claims 1 – 5, 8, 9, 12, 13 and 15 – 18 above, and further in view of Mulchandani et al. (US 5,108,767).

As discussed in greater detail above, Olovson et al. and Bergstrand et al. teach administration of a suspension of enteric coated pellets of proton pump inhibitors and a thickener. These preparations can be administered to pediatric patients either orally or through as naso-gastric tube to treat gastrointestinal disorders.

Neither reference discloses the diameter of the naso-gastric tube used.

Mulchandani et al. discloses a product that is drunk or administered by feeding tube and therefore should not have a viscosity of greater than 120 or 130 cps (centipoise; col 15, ln 18 – 21). This viscosity will allow for the composition to be administered using a size 8 or larger French (CH or Cherrier) tube and pump administration, or a size 10 French or larger tube when the preparation is administered by gravity.

It would have been obvious to the person of ordinary skill in the art at the time the invention was use a CH 8, CH 10 or larger naso-gastric tube. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the appropriate size tube used to administer the medicine will depend on the age and physical size of the pediatric patient (as pediatric patients range in age from infants to adolescents, see “pediatric” definition from Stedman's Medical dictionary) and the method by which the formulation was to be administration. Therefore, selection of the appropriate size tube for administration to various patients is within the skill of an ordinary artisan.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. This application contains claims, 6, 7, and 14 drawn to an invention nonelected with traverse in the reply filed on August 15, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW